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GB 0764342 A GB 0762229 A EP 0582396 A1
WO 94/18953 A1 WO 93/01712 A1 WO 92/11002 A1
US 4551512 A

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(54) Abstract Title
Tablets containing a bitter excipient and/or a dye

(57) A pharmaceutical tablet contains a bitter excipient and/or a dye and has a soluble coating. When placed in the mouth the soluble coating dissolves rapidly releasing the bitter excipient and/or the dye into the mouth. The bitter taste will prompt a child who has incorrectly mistaken the tablet for a sweet to spit it out, thus avoiding harm. The dye colour will confirm that the tablet has been placed in the mouth and so allow someone to confirm that the tablet has been swallowed. This is important with medication to control anti-social or self-harming conditions or to ensure that drugs such as methadone have not been hidden for later sale by a drug addict. The presence of a very bitter excipient would also encourage the tablet to be swallowed. The preferred bitter excipient is quassin, the preferred dye is methylene blue which is clearly visible even at very low concentrations and polyvinylpyrrolidone is the soluble coating of choice.

GB 2 331 702 A

TITLE: Tablets.

DESCRIPTION

This invention relates to tablets.

There is a very great danger in tablets falling into the wrong hands. Most at risk are children mistaking tablets for sweets and becoming ill or even dying as a result of taking someone else's tablets.

Another area of difficulty is in the administration of drugs by tablet to addicts, who can be skilled at secreting tablets in the mouth, so as to be able to recover the tablets later for sale to others.

An object of this invention is to provide a tablet that can mitigate against the above-identified problems.

According to the present invention it is proposed that tablets include one or both of a bitter excipient and a dye and that the tablets have a soluble coating.

The soluble coating is preferably one that will dissolve rapidly in order to release the bitter excipient and/or dye in the mouth before the tablet is swallowed. A suitable coating may be PVP (polyvinylpyrrolidone)

The bitter excipient is preferably one that is in excess of a bitterness threshold of 1:60,000. Quassin is an example of a suitable bitter excipient for use in the invention.

An aim of including a bitter excipient in tablets is to reduce the risk of children swallowing a tablet that could be harmful to them. Young children usually

do not swallow tablets immediately but lick, suck or chew medication tablets prior to swallowing. As the tablets of the invention are coated with a soluble film, the bitter excipient will be released into the mouth quite quickly on contact of the tablet with saliva in the mouth and cause the child to spit the tablet out.

Thus, according to one preferred aspect the present invention has application to medication tablets for adult administration to reduce the risk of children swallowing such tablets.

A suitable dye for use in tablets of the invention is one that will show up clearly from even a small amount being present. Methylene blue is an example of a suitable dye for use in tablets of the invention.

An aim of including a dye in tablets is to reduce the likelihood of drug addicts secreting tablets of, for example, methadone, in the mouth. The soluble coating will dissolve on contact with saliva in the mouth and release the dye quickly into the mouth. Thus, it will be very readily apparent when a drug addict has not swallowed the tablet. The same principle applies to those who are on medication to control anti-social or self-harming conditions, so that those administering the medication can ascertain whether or not the medication has been swallowed.

Another benefit of incorporation of a dye into tablets in accordance with the invention is that handling of such tablets by addicts would be quickly noticeable. Normal sweat on the hands would cause the soluble coating to dissolve and the dye would be released onto the hands.

A further advantage of the tablets of the invention containing a dye is that they will be less attractive for converting into injectable form. It is known to crush such

tablets, boil the crushed tablets with water and then inject the resulting solution. The dye will be released and will stain all utensils used.

A yet further advantage of tablets of the invention is an increase in the complexity of extracting the base drug from a tablet, especially one incorporating both the bitter excipient and dye, in a home chemistry set.

Thus, the present invention has particular application to controlled drug tablets, such as containing methadone, to reduce risk of abuse.

This invention will now be further described by means of the following Example.

Example

A methadone tablet was prepared by mixing normal tablet excipients, such as silicon dioxide, magnesium stearate and lactose, with methadone hydrochloride, methylene blue in amounts of 10mg and quassin as a bitter excipient. After pressing the mixture to form tablets, the tablets were coated with a rapidly soluble film coat of PVP such that if the tablet is held in the mouth or the hand for a certain period of time, the film dissolves to release the dye and bitter excipient.

Claims

1. A pharmaceutical tablet including one or both of a bitter excipient and a dye and having soluble coating.
2. A pharmaceutical tablet as claimed in claim 1, wherein the soluble coating dissolves in the mouth.
3. A pharmaceutical tablet as claimed in claim 1 or 2, wherein the soluble coating is polyvinylpyrrolidone.
4. A pharmaceutical tablet as claimed in claim 1, 2 or 3, wherein the bitter excipient has a bitterness threshold in excess of 1:60,000.
5. A pharmaceutical tablet as claimed in claim any one of claims 1 to 4, wherein the bitter excipient is quassin.
6. A pharmaceutical tablet as claimed in any one of claims 1 to 5, wherein the dye is noticeable even when a small amount is present.
7. A pharmaceutical tablet as claimed in any one of claims 1 to 6, wherein the dye is methylene blue.
8. A pharmaceutical tablet substantially as hereinbefore described with reference to the foregoing Example.

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Application No: GB 9826000.3 **Examiner:** Dr Lawrence Cullen
Claims searched: 1-8 **Date of search:** 29 January 1999

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

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Int Cl (Ed.6): A61K 9/20, 9/30

Other: Online: CAS Online, EPODOC, WPI

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
X	GB 0764342 A	(ABBOTT LABORATORIES) see lines 19-24 & 83-87, page 1	1, 2, 6
X	GB 0762229 A	(ABBOTT LABORATORIES) see lines 77-90, page 1	1
A	EP 0582396 A1	(PZIFER) see lines 1-35, page 2	-
X	WO 94/18953 A1	(WARNER-JENKINSON) see page 3, lines 10-20; page 6, lines 10-20	1, 3
A	WO 93/01712 A1	(IMPERIAL CHEMICAL) see final paragraph, page 3	-
X	WO 92/11002 A1	(WARNER-JENKINSON) see line 27, page 6 to line 5, page 7	1, 3
X	US 4551512 A	(STRAUB et al.) see examples 1-7b	1, 3

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.